

AMENDMENT TO THE CLAIMS

Please amend the claims without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows.

In the Claims:

1. (Currently amended) A topical patch comprising
a therapeutic compound-impermeable backing layer,
a self-adhesive amine-resistant polysiloxane matrix ~~comprising; containing; at least 1%~~
~~by weight, of~~

(i) about 5% – about 10% by weight of capsaicin or a capsaicin analog or mixture thereof as the therapeutic compound, based on the total weight of the matrix; and

(ii) about 10% – about 25% by weight of diethylene glycol monoethyl ether (DGME) based on the total weight of the matrix,

~~the therapeutic compound~~

wherein the polysiloxane matrix is a mixture of a polysiloxane of medium tack and a polysiloxane of high tack ~~and the therapeutic compound is capsaicin or a capsaicin analog or mixture thereof,~~ and

a protective film to be removed before use,

in which

- a. the matrix contains liquid microreservoir droplets comprising an amphiphilic solvent, in which the therapeutic compound is dissolved, wherein the microreservoir droplets are in an amount between 20 and 40% by weight, based on the total weight of the matrix ~~which comprise of and~~
- b. the concentration of the therapeutic compound in the microreservoir droplets is between 20 and 90% by weight of the saturation concentration

wherein the amphiphilic solvent is ~~a butanediol, 1,3-butanediol, dipropylene glycol, tetrahydrofurfuryl alcohol, diethylene glycol dimethyl ether, diethylene glycol monoethyl ether, diethylene glycol monobutyl ether, propylene glycol, dipropylene glycol, carboxylic acid esters of tri- and diethylene glycol, polyethoxylated fatty alcohols of 6–~~

~~18 Carbons or 2,2-dimethyl-4-hydroxymethyl-1,3-dioxolane, or mixtures of these solvents.~~

2. (Original) The topical patch as claimed in claim 1, in which the therapeutic compound is capsaicin.
3. (Original) The topical patch as claimed in claim 1, in which the concentration in the therapeutic compound in the microreservoir droplets is between 40 and 70% by weight of the saturation concentration.
- 4-5. (Cancelled)
6. (Original) The topical patch as claimed in claim 1, in which the microreservoir droplets comprise a viscosity-increasing additive dissolved in the solvent.
7. (Original) The topical patch as claimed in claim 6, in which the viscosity-increasing additive is a cellulose derivative or a high molecular weight polyacrylic acid.
8. (Previously presented) The topical patch of claim 7, in which the viscosity-increasing additive is ethylcellulose or hydropropylcellulose.
- 9-10. (Cancelled)
11. (Currently amended) The topical patch as claimed in claim 1 ~~claim 10~~, in which the self-adhesive amine-resistant polysiloxane matrix contains a ~~at least 5% of the therapeutic compound~~ the proportion of the microreservoir droplets in the matrix of is between 20 and 30% by weight, based on the total weight of the matrix.
12. (Currently amended) The topical patch as claimed in claim 11 ~~claim 10~~, wherein the matrix contains from about 0.5 to about 5% by weight of a silicone oil.

13. (Previously presented) The topical patch as claimed in claim 1, in which the matrix comprises
5 – 10% by weight of capsaicin or a capsaicin analog,
10 – 25% by weight of diethylene glycol monoethyl ether,
0 – 2% by weight of ethylcellulose,
0 – 5% by weight of silicone oil, and
58 – 85% by weight of self-adhesive polysiloxane and the coating weight of the matrix is between 30 and 200 g/m².
14. (Previously presented) The topical patch as claimed in claim 1, in which the matrix consists essentially of
5 – 10% by weight of capsaicin or a capsaicin analog,
10 – 25% by weight of diethylene glycol monoethyl ether,
0 – 2% by weight of ethylcellulose,
0 – 5% by weight of silicone oil, and
58 – 85% by weight of self-adhesive polysiloxane and the coating weight of the matrix is between 50 and 120 g/m².
15. (Previously presented) The patch as claimed in claim 1, in which the backing layer consists of a polyester film 10 – 20 µm thick.
16. (Original) The topical patch as claimed in claim 1, in which the backing layer consists of an ethylene-vinyl acetate copolymer.
17. (Previously presented) A method for the treatment of neuropathic pain which comprises administering the topical patch of claim 1 to a patient in need thereof.
18. (Previously presented) The topical patch as claimed in claim 11, in which the microreservoir droplets comprise a viscosity-increasing additive dissolved in the solvent.

19. (Previously presented) The topical patch as claimed in claim 18, in which the viscosity-increasing additive is ethylcellulose or hydropropylcellulose.
20. (Original) A method for the production of a topical patch as claimed in claim 1, which comprises dissolving the therapeutic compound in an amphiphilic solvent, adding this solution to a solution of a polysiloxane or the matrix constituents and dispersing, coating the resulting dispersion onto a protective layer which is removable again and removing the solvent of the polysiloxane and laminating the backing layer onto the dried matrix layer.
21. (Previously presented) The topical patch as claimed in claim 1, in which the matrix comprises 5 – 10% by weight of capsaicin.
22. (Previously presented) The topical patch as claimed in claim 21, in which the matrix comprises 8% by weight capsaicin.
23. (Previously presented) The topical patch as claimed in claim 22, in which the matrix contains ethylcellulose and silicone oil, wherein the silicone oil is dimethicone.
24. (New) The method of claim 17 wherein the administering the topical patch of claim 1 to a patient in need thereof is over a period of 1 to 8 hours.
25. (New) The method of claim 24 wherein the administering the topical patch of claim 1 to a patient in need thereof is over a period of 1 hour.